

In the matter of the petition of

AIRLINES FOR AMERICA, NATIONAL AIR CARRIER ASSOCIATION, CARGO AIRLINE ASSOCIATION, AND REGIONAL AIRLINE ASSOCIATION

for an exemption from 121.803(c)(1) and Part 121, Appendix A, First-aid Kits paragraph (2) of Title 14, Code of Federal Regulations

Exemption No. **18995**Regulatory Docket No. FAA-2021-0706

GRANT OF EXEMPTION

By letter dated August 10, 2021, Airlines for America, the National Air Carrier Association, Cargo Airline Association, and the Regional Airline Association, 1275 Pennsylvania Avenue NW, Suite 1300, Washington, DC 20004, together petitioned the Federal Aviation Administration (FAA) on behalf of their passenger and cargo airline members for an exemption from § 121.803(c)(1) and Appendix A of Part 121, Title 14, Code of Federal Regulations (14 CFR). The proposed exemption, if granted, would provide relief from the requirement to include the required amount of ammonia inhalants in a required First-Aid Kit (FAK) during periods of temporary supply shortages that are beyond operator control.

The petitioners require relief from the following regulations:

Section 121.803(c)(1) prescribes, in pertinent part, that passenger-carrying airplanes operating under Part 121 rules must carry approved FAKs that meet the specifications and requirements of Appendix A of Part 121.

Appendix A to Part 121, "First Aid Kits and Emergency Medical Kits," specifies, in pertinent part, that the minimum number of required FAKs is determined by the number of passenger seats on the aircraft, up to a maximum of 4 FAKs on aircrafts with seating of greater than 250 passengers. Appendix A also requires each approved FAK to contain ten ammonia inhalants.

The petitioners supports their request with the following information:

The petitioners state that, because FAKs are considered to be "no-go" items that must be on board for the airplane to be operated, the absence of a required FAK will result in an aircraft being inoperable. Master Minimum Equipment List (MMEL) policy provides limited relief that permits a carrier to depart when missing one of the required FAKs. However, that relief only applies for one flight.

The petitioners explain that there are myriad reasons why shortages of required FAK contents occur. These reasons include overall non-aviation demand and manufacturing shortfalls, as well as shortages of prescribed aviation packaging. There is also often little advance notice of shortages. The petitioners state that FAK refurbishers report that they are often unaware of an impending shortage until they receive a back-order notification from their supplier. As a result, operators are often unable to adequately prepare for shortages. This issue is compounded by the shelf life of certain FAK contents, as some required FAK components have a shelf life as short as twelve months. The petitioners acknowledge that Appendix A of Part 121 allows for operators to use equivalent substances when necessary. However, in this instance, the same supply shortages affecting ammonia inhalants are affecting the potential substitutes.

The petitioners stated that government regulations have had a role in causing the current shortage of ammonia inhalants. The petitioners refer to the American Society of Health-System Pharmacists (ASHP) reporting that the Coronavirus Aid, Relief, and Economic Security (CARES) Act required the FDA to recategorize ammonia inhalants, among other drugs. As a result of this recategorization, petitioners stated the FDA is now requiring ammonia inhalant manufacturers to submit applications for approval. Manufacturers have been slow to begin the application process, precipitating the current ammonia inhalant shortage.

The petitioners also state that the use of ammonia inhalants is increasingly considered to be an outdated treatment modality. The petitioners state that medical literature suggests that ammonia inhalants are no longer favored by medical professionals due to risks related to their use. The petitioners refer to the Journal of Emergency Medical Services, which has described risks related to using ammonia inhalants for reviving patients, including that patients with respiratory distress or compromised airways due to edema from infection or inflammation may acutely worsen with administration of this drug. The petitioners note that ammonia inhalants are rarely used on aircrafts. According to the petitioners, the vast majority of ammonia inhalants replaced by FAK refurbishers are replaced because of expiration, not because of use.

The petitioners also note that a contributing factor of the limited ammonia inhalant supply is the limited supply chain. According to the petitioners, only one manufacturer is approved to manufacturer ammonia inhalants. All operators and FAK refurbishers rely on that single manufacturer for ammonia inhalants. The petitioners note that they have been told by FAK refurbishers that there is no end in sight for the ammonia inhalant shortage and that FAK refurbishers have gone so far as to remove ammonia inhalants from their ordering portals.

The petitioners seek a long-term exemption from 14 CFR § 121.803(c)(1) and Appendix A of Part 121 to allow the operation of aircraft without ammonia inhalants in FAKs during periods of supply disruptions beyond the control of FAK suppliers, FAK refurbishers, and operators.

The petitioners assert that airlines and their kit suppliers have been able to address similar temporary shortages in Emergency Medical Kits (EMKs) through a variety of accommodations and FAA exemptions.

The petitioners assert that, absent this relief, operators will soon be unable to have FAKs complete with ammonia inhalants. As a result, the petitioners contend operators will have to take the affected aircrafts out of service, causing potentially significant disruptions to air travel. The petitioners state that granting this exemption would serve the public interest by ensuring that air service continues uninterrupted. The petitioners state the public would not likely be harmed by not having ammonia inhalants onboard aircraft, as ammonia inhalants are very infrequently used.

The petitioners request that the exemption apply to flights conducted outside the United States, in order to avoid disruptions in international operations. The petitioners note that the International Civil Aviation Organization (ICAO) standard calls for aircraft to be equipped with "accessible and adequate medical supplies," and recommends that these supplies include "one or more first-aid kits for the use of cabin crew in managing incidents of ill health." ICAO does not recommend the inclusion of ammonia inhalants in FAKs. As a result, the petitioners believe the requested exemption would not violate ICAO standards.

The FAA's analysis is as follows:

A summary of the petition was published in the *Federal Register* on September 16, 2021, (86 FR 51713). There were no comments received that were relevant to this exemption.¹

The documented ammonia inhalants shortage creates the possibility that a significant number of aircraft would be unable to meet the requirements of 14 CFR § 121.803(c)(1) and Appendix A of Part 121, resulting in operators being required to take affected aircraft out of service. This potential impact on scheduled operations could be detrimental to air transportation and would affect consumers. In addition, the FAA is aware that ammonia inhalants are used infrequently on board aircraft. Moreover, the FAA has granted relief from certain items listed in Appendix A that are required in EMKs. Based on the foregoing, the FAA has determined the relief this exemption provides is in the public interest and would not adversely affect safety, provided all operators that take advantage of this relief comply with the conditions and limitations of this exemption.

When conducting operations in accordance with this exemption, crewmembers must be aware of the terms of this exemption and remain prepared to respond to emergencies without the use of ammonia inhalants. In addition, each certificate holder that operates under this exemption must ensure a copy of this exemption and Letter of Intent remains both in the certificate

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¹ The FAA did receive one comment in response to this petition. However, it was not related in any way to this petition. *See* J.N. Passty, Comment on Exemption Petition from Airlines from America, Cargo Airline Association, National Air Carrier Association, & Regional Airline Association (Oct. 5, 2021), https://www.regulations.gov/comment/FAA-2021-0706-0003.

² See Exemption No. 10690 (Jan. 25, 2013) granting relief for Atropine, Dextrose, Epinephrine, and/or Lidocaine due to a shortage in supply.

holder's Operations Specifications³ and onboard each aircraft that lacks the required number of ammonia inhalants. Furthermore, this exemption will require certificate holders to monitor the availability of ammonia inhalants and, should they become available to FAK suppliers or refurbishers, certificate holders operating under this exemption must refurbish the FAK with the missing ammonia inhalants at the next scheduled refurbishment date. Compliance with these provisions will ensure operations that occur under this exemption will not adversely affect safety because crewmember awareness and preparation, combined with potential refurbishments of the FAK supply, will limit the level of risk that this exemption could present. Lastly, as noted above, the petitioners request that the exemption apply to flights conducted outside the United States. Because ICAO does not recommend the inclusion of ammonia inhalants in FAKs and because compliance with the conditions of this exemption will not adversely affect safety, this exemption would not violate ICAO standards.

Airlines for America, Cargo Airline Association, the National Air Carrier Association, and the Regional Airline Association cannot receive an exemption from FAA operating regulations because these associations are not authorized to conduct operations. To operate under this exemption, each affected certificate holder must submit to the FAA a request in the form of a Letter of Intent to use this exemption and affirm its intentions to comply with the conditions and limitations of this exemption. Consistent with this decision, Condition and Limitation No. 1 requires members of Airlines for America, Cargo Airline Association, the National Air Carrier Association, or the Regional Airline Association that wish to exercise the relief provided in this exemption to submit a Letter of Intent prior to conducting any operation under Exemption No. 18995. Letters of Intent must be submitted to the Federal eRulemaking Portal: Go to http://www.regulations.gov and submit Letters of Intent under Docket Number FAA-2021-0706. Certificate holders should retain documentation to verify proper and timely submission of the Letter of Intent.

This exemption contains relief that applies only to operations for which it is necessary. The petitioners represent a broad group of operators, not all of which might need relief from § 121.803(c)(1) and the Appendix A requirement for a certain number of ammonia inhalants per aircraft. In the interest of tailoring this exemption to apply only as appropriate, this exemption will apply only to members of petitioners' organizations that operate under 14 CFR Part 121. For certificate holders authorized to conduct operations under Part 121 for certain flights and 14 CFR Part 135 for other flights and that use aircraft for which it cannot supply ammonia inhalants, this exemption will provide relief from § 135.177(a)(1), but only for those operations that require such relief.

The FAA's Decision

In consideration of the foregoing, I find that a grant of an exemption is in the public interest. Therefore, pursuant to the authority contained in 49 U.S.C. §§ 106(f), 40113, and 44701, delegated to me by the Administrator, I grant those members only of the Airlines for America, Cargo Airline Association, the National Air Carrier Association, or the Regional Airline Association authorized to conduct operations under Part 121 and who submit a Letter of Intent under Docket Number FAA-2021-0706 (in the form and manner described below) an

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³ See 14 CFR § 119.49.

exemption from the requirement to carry the required number of ammonia inhalants in each first-aid kit referenced at 14 CFR § 121.803(c)(1) and Appendix A. In addition, I grant those members only of the Airlines for America, Cargo Airline Association, the National Air Carrier Association, or the Regional Airline Association authorized to conduct operations under Part 121 for certain flights and 14 CFR Part 135 for other flights who submit a Letter of Intent under Docket Number FAA-2021-0706 (in the form and manner described below) an exemption from the applicable requirement to carry the required number of ammonia inhalants in each first-aid kit referenced at 14 CFR §§ 121.803(c)(1) and Appendix A, or 135.177(a)(1)(iii). Certificate holders exercising the relief provided by this exemption must comply with all conditions and limitations listed below.

Conditions and Limitations

- Certificate holders that wish to utilize the relief provided by this exemption must submit a Letter of Intent under Docket No. FAA-2021-0706. The letter should be submitted to the Federal eRulemaking Portal under Docket No. FAA-2021-0706. Go to http://www.regulations.gov and follow the online instructions for submitting documents electronically. The Letter of Intent must state the certificate holder's intention to exercise the relief granted in this exemption and affirm the intention to only conduct operations in a manner consistent with all conditions and limitations herein.
- 2. A copy of this exemption with the expiration date and Letter of Intent must be carried on board each aircraft operating with a first-aid kit (FAK) that does not include the required number of ammonia inhalants as required by Appendix A of Part 121 or § 135.177(a)(1)(iii).
- 3. Certificate holders must receive authorization from their assigned principal operations inspector (POI) in operations specification (OpSpec) A005 prior to exercising the privileges of this exemption.
- 4. When the aircraft on which the crew is assigned duty is equipped with one or more FAKs lacking ammonia inhalants, operators must inform crewmembers that one or more FAKs on board that aircraft does not contain the number of ammonia inhalants required by Appendix A of Part 121 or § 135.177(a)(1)(iii), as applicable.
- 5. Should ammonia inhalants become available to FAK suppliers or refurbishers, exemption holders must refurbish the FAK with the missing ammonia inhalants at the next scheduled refurbishment date.
- 6. This exemption may be used for flights conducted outside of the United States.

The Effect of the FAA's Decision

This exemption terminates on February 28, 2024, unless sooner superseded or rescinded.

To request an extension or amendment to this exemption, please submit your request by using the Regulatory Docket No. FAA-2021-0706 (http://www.regulations.gov). In addition, you should submit your request for extension or amendment no later than 120 days prior to the expiration listed above, or the date you need the amendment, respectively.

Any extension or amendment request must meet the requirements of 14 CFR § 11.81.

Issued in Washington, D.C., on February 9, 2022.

/s/
Robert C. Carty
Acting Executive Director, Flight Standards Service

Enclosures